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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,858	03/28/2000	Paul Proost	49674	5522

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/537,858

Applicant(s)

PROOST ET AL.

Examiner

Prema M Mertz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Amended claims 28-30 (2/18/04) and previously pending claims 24-27 are under consideration.
2. Receipt of Applicants' arguments and amendments filed on 10/2/03 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/18/04 and 10/2/03:
(i) the objection to the drawings.
4. Applicant's arguments filed on 2/18/04 and 10/2/03 have been fully considered but were persuasive in part. The issues remaining are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

6. Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph.

This rejection is maintained for reasons of record set forth at page 4 of the previous Office action (3/31/2003).

Applicants appear to have misunderstood the Examiner's rejection. There is no requirement for a new sequence listing as argued by Applicants. With respect to claim 24, line 3, for example, which recites "residues 2-68 of....SEQ ID NO:2", the recitation is improper and incorrect because SEQ ID No:2 consists of 66 amino acids. It is suggested that the claims be amended to recite "SEQ ID NO:1" which is 68 amino acids. Therefore, claims 24-27 should be amended to recite "residues 2-68 of.....SEQ ID

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NO:1”, “residues 3-68 of.....SEQ ID NO:1”, “residues 4-68 of.....SEQ ID NO:1”, “residues 5-68 of.....SEQ ID NO:1”, respectively, to obviate this rejection.

Claims 28-30 are rejected insofar as they depend on claims 24-27 for their limitations.

This rejection is maintained for reasons of record set forth at page 4 of the previous Office action (3/31/2003).

Claim Rejections - 35 USC § 102(b)

7. Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Noso et al. (J. Immunol. 1996).

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action (3/31/2003).

Applicants argue that in applying the rejection, the Examiner is improperly ignoring limitations in the claims that require that the polypeptide be both isolated and have chemokine antagonistic activity. Applicants also argue that Noso is unable to demonstrate chemokine antagonistic activity in the fraction collected, which comprises RANTES amino acids 3-68 along with other impurities. However, contrary to Applicants arguments, the purification or isolation of the RANTES product is not the issue here, because the reference describes the same RANTES protein. Irrespective of the purity of the product, the protein of the prior art reference is identical to the instantly claimed protein. Furthermore, Applicants arguments are not directed to a showing that the protein of the prior art is materially different than the claimed protein, but are merely attempting to question the activity of the prior art protein based on experimental methods. The RANTES protein disclosed in the Noso reference is identical to the claimed RANTES product, and this fact has been proven unequivocally by the Examiner. The purity of the RANTES product is

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irrelevant here, because the Noso reference clearly shows that the product of the reference is the RANTES product claimed in the instant application. The instant claims encompass the product of the Noso reference and Applicants have not shown evidence to the contrary. It is irrelevant that the reference is unable to demonstrate the claimed activity, because the reference is purely being relied upon to show unequivocally that the reference RANTES protein and the claimed RANTES protein are the same protein. Applicants have not shown the error in the rejection but are instead misconstruing the application of the reference and arguing about the activity of the RANTES protein of the reference.

The Examiner has not improperly relied upon Noso et al. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." see In re Papesch, 315 F. 2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Claim Rejections - 35 USC § 102(e)

8. Claims 24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Offord et al. (US Patent No. 6,168,784).

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action (3/31/2003).

Applicants argue that Offord discloses N-terminally modified RANTES derivatives that have chemokine antagonistic activity and that Offord does not disclose that an isolated polypeptide, i.e., not chemically modified, possesses such activity. Applicants therefore argue that the reference does not disclose all of the elements of the claims as required for anticipation under section 102. However, contrary to Applicants arguments, the instant claims recite "comprising" language, which is open-language and encompasses the N-terminally modified RANTES derivatives of the prior art reference.

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Claim Rejections - 35 USC § 103

9. Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (1996).

This rejection is maintained for reasons of record set forth at pages 7-8 of the previous Office action (3/31/2003).

Applicants argue that the Examiner does not provide support for any belief that truncations in RANTES would inhibit any models of inflammation in view of Gong's teachings that RANTES polypeptides consisting of residues 6-68, i.e., the smallest truncation shown by Gong, showed the least displacement and therefore the least amount of inhibition in the assays used to evaluate efficacy. Therefore, Applicants argue that contrary to the Examiner's assertion, one of skill in the art would not be motivated to make truncations with fewer than six amino acids to obtain an effective chemokine inhibitor. Additionally, Applicants argue that "obvious-to-try" is an incorrect standard where the claimed result, the generation of compounds and pharmaceutical compositions with chemokine antagonistic activity, is not at all predictable. See, *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir.1990). However, contrary to Applicants arguments, if Gong specifically disclosed amino-terminally truncated RANTES 2-68, 3-68, 4-68 and 5-68, lacking amino-terminal amino acid residues 1, 1-2, 1-3, or 1-4 of a mature RANTES polypeptide having antagonistic activity and pharmaceutical compositions thereof, the instant rejection would be a 35 USC 102 rejection rather than a 35 USC 103 rejection.

Claim Rejections - 35 USC § 103

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10. Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rollins et al. (U.S. Pat. No. 5,739,103) in view of Proudfoot et al (1996).

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action (3/31/2003).

Applicants argue that the Examiner points to no teaching in either Rollins or Proudfoot that would motivate one of skill in the art to generate the specific truncations claimed with the expectation of obtaining truncations with chemokine antagonistic activity and therefore, contrary to the Examiner's assertion, one of skill in the art would not be motivated to make truncations with fewer than six amino acids to obtain an effective chemokine inhibitor. However, contrary to Applicants arguments, this rejection is a 35 USC 103 rejection, not a 35 USC 102 rejection. If each of the references taught the limitations of the instant claims, the instant rejection would be a 35 USC 102 rejection, not a 35 USC 103 rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 31, 2004